



November 30, 2015

Pharmaceutical Working Group
c/o Angelo J. Bellomo, REHS, QEP,
Deputy Director for Health Protection
5050 Commerce Drive
Baldwin Park, CA 91706

Dear Mr. Bellomo and Members of the Working Group:

Thank you for including the Healthcare Distribution Management Association (HDMA), the national association representing primary healthcare distributors, as an observer in the Pharmaceutical Working Group's Technical Advisory Committee. As the Pharmaceutical Working Group and the Los Angeles County Board of Supervisors continue its discussions and consideration of a County Ordinance regarding the disposal of unused prescription drugs and sharps, HDMA submits the following comments and the attached redlined draft ordinance for your consideration.

Primary healthcare distributors are the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and other settings of care nationwide. HDMA and its members work daily to efficiently deliver life-saving medicines and healthcare products, provide value and efficiency, and achieve an estimated \$42 billion in cost savings each year to our nation's healthcare system.

HDMA and our members recognize the importance of efforts to ensure the safe, secure, and convenient disposal of unused, unwanted, or expired medications and sharps. While HDMA distributor members do not manufacture pharmaceuticals or interact directly with patients¹, primary healthcare wholesale distributors are dedicated to responsibly disposing of expired or damaged pharmaceuticals returned from our customers and within member warehouses as permitted by law.

HDMA members are also finding ways to lend their expertise in relation to their position in the supply chain, and are trying to raise awareness and encourage the safe drug disposal of unwanted or expired medications. As part of public policy initiatives, HDMA member companies have also engaged in a variety of activities such as assistance with public service announcements, customer invoice messaging, educational opportunities at business meetings, and other educational materials to provide our pharmacy customers with information and resources to help their patients understand their options for safe disposal.

¹ Note that the core business of pharmaceutical distributors is wholesale distribution of drug and other healthcare products; however, some of HDMA's member companies do have other, separate business units that are engaged in other supply chain roles.

Additionally, HDMA shares some of the concerns that have been expressed by other stakeholders, such as the confusion, regulatory burden, and extra costs that may result from a county-by-county approach to product stewardship for sharps and pharmaceuticals. While we acknowledge Los Angeles County's interest in protecting its immediate environment and its citizens, we also hope that this could be accomplished through a partnership approach with the state Legislature, in order to ensure uniformity for consumers and businesses.

Moreover, we want to bring to your attention a newer technology enabling at-home disposal for the end-user via a sealable, disposable, biodegradable pouch that some of our member companies currently distribute to healthcare providers. The technology is highly effective in adsorbing and firmly binding pharmaceuticals, rendering them inactive and ineffective for misuse and safe for the environment. This technology is currently being piloted in Florida and we believe it may offer local and state governments, and individual consumers, a more practical option of disposal. Further, HDMA believes that safe disposal methods such as this may eliminate leftover medicines in the home, and prevent unauthorized use or diversion, and subsequent abuse, of prescription medications.

With respect to the LA County Proposed Ordinance, we attach for your consideration, a redlined version with our suggested edits and comments. We summarize some key areas below:

Definition of "Producer"

It appears that the County recognizes the role of the wholesale distributor in the supply chain via its requirement to report annually the producers from whom pharmaceuticals are purchased. However, we also note that the county uses the Alameda County definition of producer which could have implications for distributors, in the event that a true "producer" (e.g., manufacturer) is not participating in a product stewardship program. Subsection (d) of the defining of producer concerns HDMA members, because, in many cases, the primary wholesale distributor will be bringing the product into the County. Primary distributors purchase products from manufacturers, take title to the products, store, handle, pick pack and ship, selling them to virtually every pharmacy setting (independent, chain, hospital, institutional, clinical). This unique business model ensures the safety and efficiency of the U.S. pharmaceutical supply chain and enables patients to have confidence that their pharmacy or provider will have the medicine they need, when they need it.

As such, we encourage you to adopt the definition of producer used in the San Francisco County Ordinance on the same topic, or, in lieu of that, to please clarify that wholesalers are not at risk under the proposed ordinance, simply by default if the manufacturer of the product is not in compliance with the new requirements.

Product stewardship proposals target reduction of waste and elimination from the environment or products introduced into commerce. The obligation for such take-back or disposal efforts related to pharmaceuticals should lie with the original manufacturer of the product in its finished dosage form. In other words, the manufacturer that first introduces the product into commerce. These original manufacturers are in the best position to manage product stewardship activities and ways to reduce waste generation, rather than those entities in the middle of the pharmaceutical supply chain that "handle" such as wholesalers, private label distributors, repackagers, etc.

Repackager and Private Label Distributors

As you are aware, other County Ordinances have recognized the utility of exempting private label products at the retail level, as well as wholesalers. Exempting private label distributors and repackagers of finished dose products manufactured by an “original” manufacturer simply recognizes what has already been targeted in these other exempted groups – these specialized types of entities and business arrangements are not responsible for the product’s first entry into the environment, and the original manufacturer is in a better position to manage and orchestrate product stewardship plans for their own products.

We note that the LA County Proposal currently includes a reporting requirement for repackagers and private labelers, but again, fails to state that these entities (which are not the true manufacturers of the products) are not responsible. Additionally, the proposal requires these entities to provide notice about the original manufacturer’s participation in a product stewardship program, but omits any mechanism for the repackager or private labeler to obtain such information from the manufacturer. Instead, we recommend that the repackager or private labeler simply report their respective producer lists to the County, but suggest that this notice requirement be amended to reflect that these entities will not have that primary information, since the requirement is for the manufacturer to report to the County.

HDMA members are committed to working with our supply chain partners and government officials to ensure the safe and secure disposal of unused, unwanted, or expired medications, particularly as it is related to the prescription drug abuse epidemic. Safe Disposal is just one layer in wholesaler’s multilayer approach to combatting prescription drug abuse.

Thank you for your consideration of our views and attention to our comments. Should you have any questions or need additional information, please contact me at egallenagh@hdmanet.org or 703-885-0234.

Sincerely,

A handwritten signature in blue ink, appearing to read "E. Gallenagh", with a stylized flourish at the end.

Elizabeth A. Gallenagh, Esq.
Senior Vice President, Government Affairs
and General Counsel